

## **REMARKS**

Claim has been amended to recited "same anti-cancer activity" rather than "same activity". Applicant has added new claims 17-21. Support for these new claims is found in the claims as originally filed. No new matter is added.

### **Rejections under 35 U.S.C. §112, second paragraph**

The Examiner rejected claims 1 and 5 as allegedly indefinite for reciting "same activity". Claim 1 has been amended to recite "same anti-cancer activity" as SEQ ID NO:2. Claim 5 refers back to claim 1.

The present specification describe the anti-cancer activity of SEQ ID NO:2, and one skilled in the art can readily perceive the meaning of claim 1. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

### **Rejections under 35 U.S.C. §112, first paragraph (written description)**

The Examiner rejected claims 1 and 5 as allegedly failing to meet the written description requirement. The Examiner argued that the specification does not "teach which residue(s) or domain(s) is required for the activity."

As the specification explains, SEQ ID NO:2 is a novel, non-obvious of TRAIL and has greater anticancer activity than TRAIL. However, once one has been taught how to produce SEQ ID NO:2 by the present application, one skilled in the art can apply what is known about TRAIL to produce variants of SEQ ID NO:2 such as deletion, insertion and substitution variants. Those skilled in the art have considerable knowledge of TRAIL from such teachings as those of WO 01/00832, WO 03/029420 and U.S. Patent No. 6,740,739.

In view of the forgoing, Applicant respectfully requests that the rejections based on the written description requirement of 35 U.S.C. §112, first paragraph be reconsidered and withdrawn.

### **Rejections under 35 U.S.C. §102**

The Examiner rejected claims 1 and 5 as anticipated by Pitti et al. (*J Biol Chem* 271:12687, 1996). The Examiner stated that the difference between SEQ ID NO:2 and the polypeptide (Apo-2 ligand) disclosed by Pitti et al. is a deletion of 19 amino acids at the C-terminus of (presumably) SEQ ID NO:2. However, there are additional differences. For example, the polypeptide of Pitti et al. has 134 amino acids at its amino terminus that are not present in SEQ ID NO:2. Moreover, present claim 1, part 3 is drawn to a “protein derived from SEQ ID No:2, which is obtained by substitution, deletion, or addition of one or several amino acid residues in the amino acid sequence of SEQ ID No:2, and which has the same anti-cancer activity as that of SEQ ID NO:2” (emphasis added). The Examiner has not indicated any basis for concluding that the anti-cancer activity of the Apo-2 ligand disclosed by Pitti et al. is the same as that of SEQ ID NO:2.

In view of the forgoing, Applicant respectfully requests that the rejections under 35 U.S.C. §102 be reconsidered and withdrawn.

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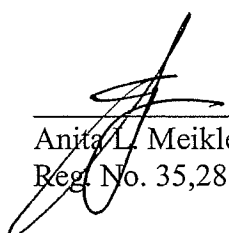
### Conclusion

It is believed that he pending claims are in condition for allowance.

The fees in the amount of \$50.00 for excess claim fees and a \$555.00 check for the Petition for Extension of Time fee are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing attorney-docket no. 20807-0002US1.

Respectfully submitted,

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